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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,557	12/04/2003	Leila Toumi	236689US0	5460

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EXAMINER	
SILVERMAN, ERIC E	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
04/10/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/726,557	TOUMI ET AL.	
	Examiner	Art Unit	
	Eric E. Silverman, PhD	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-9 and 11-26* is/are pending in the application.

4a) Of the above claim(s) *12-14 and 18-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-9,1-17,23-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' response, filed 2/20/2008, has been received. Claims 1 – 5, 7 – 9, and 11 – 26 are pending. Claims 12 – 14, and 18 – 22 are withdrawn as non-elected. Claims 1 – 5, 7 – 9, 11, 15 – 17, and 23 – 26 are treated on the merits in this action.

Election/Restrictions

This application contains claims 18 – 22, drawn to an invention nonelected with traverse in the reply filed on 4/3/2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 – 5, 7 – 9, 11, 15 – 17, and 23 – 26 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the combination of agents and polymer (phenylpropylselsesquioxane) shown in the examples, does not reasonably provide enablement for any other polymer, or any other combination of agents with this polymer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. . Undue experimentation is determined using the factors enumerated in MPEP 2164.01(a). All of these factors have been considered, and the most relevant are discussed below.

- *The breadth of the claims.* The claims are drawn to particles having a synthetic polymer with an aryl group directly attached to a polyorganosiloxane, and a glass transition temperature greater than 45 C in and an active agent with a molecular weight less than 1,000, the active having at least one aromatic, carbocylic, heterocyclic, monocyclic, or fused polycyclic group. In their broadest sense, the claims relate to a wide variety of polymers, because there is no limitation regarding how much of the polymer's total structure must be aryl-polyorganosiloxne. That is, the aryl polyorganosiloxane may be incorporated into a copolymer in any amount, even trivial amounts, and still read on this claim. Further, there is no restriction as to the type of comonomer or comonomers that could be a component of the polymer. Thus, the claimed polymer could include comonomers having properties ranging from cationic, anionic, hydrophilic, hydrophobic, rigid, thermoplastic, etc. The claims include block copolymers, graft copolymers, random copolymers, alternate copolymers, and gradient copolymers of any number of comonomers, so long as there is at least one polyorganosiloxane comprising aryl groups linked directly to the silicon atoms component Further, the aryl group attached directly to the silicon atom may be any type of aryl groups, including phenyl, pyridyl, napthyl, etc. and may have any substituents under the sun. There are no limitations regarding the molecular weight of the polymer, which may

therefore be from about a hundred to over a million Daltons. No limitation regarding the type of excipients that may be added is present.

- *The nature of the invention.* Applicants have made particles comprising active agents and phenylpropylsilsesquioxane polymer. These agents allegedly are useful for applications where active agents having a molecular weight less than 1,000 are desired, and it is further desired that the active agents do not leach out of the particle, nor do any materials that may degrade the active agent leach into the particle.
- *The state of the prior art.* The art does not recognize the equivalence between all polymers having aryl groups, nor does it recognize the equivalence (as far as degredation and leaching). With regard to leaching, the art recognizes that rate of movement of a molecule in a condensed phase is related to the inverse square of its hydrodynamic volume, which is in turn related to the molecules molecular weight.
- *The level of one of ordinary skill.* The relevant art is chemistry. The person of ordinary skill in the art has a bachelors degree, or the equivalent thereof (see C&EN July 24, 2006, which shows that bachelors degrees in chemistry are awarded about 5 times more frequently than PhD degrees). This is a fair estimate of the person of skill, since many artisans have completed less than a bachelors degree (for example, a technical degree). Considering this level of education and technical experience, the artisan has the ability to follow standard operating

procedures, but does not have the skill to optimize those procedures. The artisan recognizes the names and structures of various materials used in the art, but does not know how to substitute one material for another without explicit instruction. The artisan knows how to take routine measurements to determine the properties of materials, but is unable to determine, without explicit instruction, other materials that are likely to have the same or similar properties to those that are measured.

- *The level of predictability in the art.* The art of protecting materials from degradation is quite unpredictable. There are a wide variety of means by which materials may degrade, including oxidation by air and similar materials, epimierization, reaction with water, reaction with impurities, photodegradation, thermal degradation, and so forth. These mechanisms may act individually or in combination. The applicability of one or more of these degradation mechanisms is not clear *a priori*. Further, even when degradation of an active agent is noted, it is often not easy to determine what degrading mechanism is responsible. Indeed, it is recognized that incorporation of materials into solid polymer articles (particles) is problematic because the incorporated material tends to migrate or leach out of the particle. Specification page 2. For this and other reasons, the art recognizes that it is very difficult to obtain satisfactorily encapsulated agents. See specification page 2.

- *The amount of direction provided by the inventor and the existence of working examples.* The inventor only alleges that any polymer having aryl groups and a Tg over 45 C will solve the problem of degradation and leaching of actives from particles. The specification provides no nexus between these polymer properties and the mechanism by which the problem is allegedly solved. The working examples show the making of particles with phenylpropylselsquioxane polymer, but do not actually show how to use the particles in order to obtain the stated effects (that is, to use the particles such that leaching and degradation is prevented). Indeed, even in the inventors example, the active agent sorghum leaches out of the particle at 10% per month. Specification page 16. Accordingly, it cannot be said to be clear that any other polymer would be able to make a useful invention, namely, one that resists leaching according to the teachings of the disclosure. Further, the specification gives no guidelines as to how to manipulate the particles and retain or achieve the desired benefits. What solvents or media may the particles be dissolved or dispersed in to prevent leaching and degradation? It the particles are to be tableted, what compression forces may be used? At what heat (and for how long) is thermal degradation prevented? And how do the answers to these questions changed when the active agent or polymer are varied? These are just some of the questions which are not answered by the instant disclosure.

- *The quantity of experimentation needed to use the invention based on the content of the disclosure.* In order to use the invention, the artisan would first have to determine, for each active agent, what degradation mechanisms are likely to cause degradation. The artisan would then have to determine what polysiloxanes with aryl groups would serve to prevent these mechanisms. Subsequently, the artisan would have to determine how the particle could be used so that no degradation or leaching actually occurs.

Since the specification does not give any useful guidance on how to go about the required experimentation, and because the art is unpredictable and the skill level is fairly low, the amount of experimentation needed to use the invention is clearly undue. As such, the invention is not fully enabled by the disclosure.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive. Applicants' first argue that "[c]laim 1 clearly defines an active principle, a synthetic polymer, and respective amounts of those components." Response page 8. These remarks are not well understood because the issue at hand is not definiteness, but whether the scope of the invention is enabled.

Applicants' then argue that the artisan could perform the manufacturing and evaluation methods of the examples with compounds and compositions other than those explicitly defined, and that such experimentation would not be undue. Applicants

point out that the test is not whether any experimentation is required, but whether the required experimentation is undue.

In response, it is noted that Applicants' statement that the required experimentation would not be undue is conclusory, and is unsupported by evidence or technical reasoning. Here, the evidence of record suggests that the skill in the art is low, and that the art is highly unpredictable. Applicants have neither presented evidence to show otherwise, nor averred that the Office's interpretation of the evidence is incorrect. A low level of skill and high degree of unpredictability both suggest that experimentation is undue. Furthermore, Applicants' suggestion that the artisan could use other compounds and compositions in the methods of the examples to determine for themselves what works is merely an invitation for the artisan to experiment and determine what the invention is. The artisan cannot be expected to assay every known polymer and active agent according to the invention to determine which ones are usable. *Genetech*, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable." Accordingly, a mere invitation to the artisan to experiment is not a basis for patentability. It is incumbent upon the Applicant, not the artisan, to define what is and what is not usable in the invention.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
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